510(K) SUMMARY

Corentec Co., Ltd.

LOSPA IS Spinal System

22nd Aug, 2013

SEP 19 2013

ADMINISTRATIVE INFORMATION

Manufacturer: Corentec Co., Ltd.
247 Giro-ri, Ipjang-myeon, Seobuk-Gu
Cheonan-si, Chungchongnam-do, 331-822 South Korea
Telephone: +82-41-585-7114
Fax: +82-41-585-7113

Official Contact: J.S. Daniel
Project Engineer/Manager – RA & QA
Corentec Co., Ltd
8th Chungho Tower, 748-1 Banpo 1 Dong
Seocho Gu, Seoul, Korea 137-040
Ph: +82 70 4393 3819
Fax: +82 2 3445 5467
Email: jsdaniel@corentec.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	LOSPA IS Spinal System
Common Name:	Pedicle Screw Spinal System
Classification Regulations:	21 CFR 888.3070
Regulatory Class:	Class II
Product Codes:	MNI, MNH, KWQ
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Posterior Spinal Devices Branch

INTENDED USE

The LOSPA IS Spinal Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic,

lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

When used as an anterior screw fixation system, the LOSPA IS Spinal Systems are indicated for patients with degenerative disc disease which is defined as back pain of the discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudarthrosis, or revision of failed fusion attempts.

DEVICE DESCRIPTION

LOSPA IS Spinal System cleared under K092076 is modified for inclusion of 5.5 diameter rods. The rod link (type –B) & pedicle screws are also modified to include 5.5 diameter rods. The rods are available in straight and pre bent configurations for optimal anatomical adjustment. The rod ends are either flat or bullet nosed. The bullet nose might eases navigation through soft tissue. The subject and predicate devices are similar in design, material, specification and manufacturing and are not altered and remain the same as discussed in K092076. Only the prebent rod is additionally available in CoCrMo alloy. *The set screw used in the pedicle screw in is the same as approved in K092076, made up of Ti alloy (ASTM F 136) and can be used with both 5.5 mm and 6.0 mm rod system.*

The LOSPA IS spinal system is this submission comprises of the following components,

A. Pedicle Screws (Monoaxial & Polyaxial), standard and guided types, with screw diameters from 4.0 mm to 8.5 mm and length ranging from 20 mm to 55 mm, made up of Titanium Alloy (ASTM F 136).
B. Straight Rods of diameter of 5.5 mm (Standard) made up of Titanium Alloy (ASTM F 136).
C. Prebent Rods of diameter 5.5 mm (Standard & Bullet types) made up of Titanium Alloy (ASTM F 136) & CoCr (ASTM F 1537)
D. Rod link 5.5 *(Type B)* made up of Titanium Alloy (ASTM F 136).

All the components are manufactured from medical grade titanium alloy (ASTM F 136) & CoCrMo alloy (ASTM F 1537).

SUBSTANTIAL EQUIVALENCE

The LOSPA IS Spinal System is similar to the 510(k) cleared devices as mentioned below with respect to indications, design, operating principles and material.

- AEGIS & AEGIS II Spinal Systems (*Renamed as LOSPA IS Spinal System*) cleared under K092076, manufactured by Corentec Co., Ltd.
- Synergy VLS cleared under K974749 (& K081952), manufactured by Biomet Spine *(Interpore Cross International)*
- Moss Miami cleared under K022623(& K964024), manufactured by DePuy Acromed
- OPTIMA cleared under K031585 (& K071880), manufactured by U & I Corporation.
- Rogozinski Spinal Rod System, cleared under K983904, manufactured by United States Surgical Corporation
- APEX Spine System CoCr Rods, cleared under K102488, manufactured by SpineCraft,LLC
- Firebird Cobalt Chrome Rod, cleared under K092624, manufactured by Blackstone Medical, Inc.
- EXPEDIUM Spine System, cleared under K130877, manufactured by DePuy

PERFORMANCE DATA

Corentec's LOSPA IS Spinal System modified components were subjected to a series of testing protocols to document the performance of the components to demonstrate substantial equivalence. The performance testing was conducted as per international standards, ASTM F1717 & ASTM F1798. The static and dynamic testing results demonstrated that the subject device performed either similar or better than comparable predicate devices, there by establishing substantial equivalence for performance.

STERILIZATION & PACKAGING

Similar to the predicate devices, the LOSPA IS Spinal System components are supplied non sterile. Hence all implants and instruments used in the surgery must be sterilized by the hospital, prior to use, as mentioned in the IFU.

Any differences in technological characteristic between the subject and predicate devices do not raise new issues of safety or efficacy. Overall, the LOSPA IS Spinal Systems has the following similarities to the predicate devices:

- Has the same intended use,
- Use the same operating principles,
- Incorporate the same basic designs,
- Incorporate same/similar materials, and
- Has similar packaging materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 19, 2013

Corentec Company, Limited
Mr. J.S. Daniel
Project Engineer / Manager – RA & QA
8th Chungho Tower, 748-1 Banpo 1 Dong
Seocho Gu, Seoul 137-040
South Korea

Re: K132644
Trade/Device Name: LOSPA IS Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWQ
Dated: August 23, 2013
Received: August 26, 2013

Dear Mr. Daniel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K132644

Device Name: LOSPA IS Spinal System

The LOSPA IS Spinal Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

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Prescription Use: X AND / OR Over-The Counter Use: _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Colin O'Neill

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132644